

REMARKS

The present application is directed to methods for the treatment of a disorder or condition and for the controlled release of therapeutic, prophylactic, or diagnostic agents by administering a biocompatible, polymerizable, macromer composition containing at least one NO carrying region or NO modulating compound. Claims 18 and 20-24 are pending. Applicants hereby respectfully request entry of the amendments to Claims 18 and 20. No new matter is introduced by the amendments. Reexamination and reconsideration of the application are requested in view of the claim amendments and following remarks.

Non-statutory Double Patenting Rejection

The Examiner provisionally rejected Claims 20-23 of the present application under the judicially created doctrine of obviousness-type double patenting as unpatentable over Claims 20-23 of co-pending U.S. Patent Application No. 10/129,418, which is commonly owned with the present patent application. The Examiner asserted that Claim 20 of the present application is not patentably distinct from Claim 20 of the co-pending application.

To applicants' knowledge, no Office Action has yet been issued in U.S. Patent Application Serial No. 10/129,418. Applicants will resolve any double-patenting issues that may arise when allowable subject matter is found in both the present application and the cited co-pending application.

Claim Rejections under 35 U.S.C. §103(a)

In the Final Office Action dated March 24, 2004, the Examiner maintained the rejection of Claims 18 and 20-24 under 35 U.S.C. §103(a) as *prima facie* obvious over *Roth et al.* (U.S. Patent No. 5,879,713) in view of *Trescony et al.* (U.S. Patent No. 5,994,444). Applicants respectfully submit that the amendments to the claims overcome the rejection.

Roth et al. teaches a polymeric material for delivery of biologically active molecules, wherein a hydrogel is used to entrap and homogeneously disperse the biologically active

molecules for release after polymerization of the hydrogel. *Trescony et al.* teaches a polymeric material impregnated with a nitric oxide donor for continuous release of nitric oxide upon hydration of the material. Both *Roth et al.* and *Trescony et al.* teach incorporation of biologically active molecules into the polymeric material by entrapment (column 5, lines 13-15, 22-23, and 30-36 in *Roth et al.*), dispersion, or embedding (column 5, lines 35-39, column 6, lines 6-7 and 32-34 in *Trescony et al.*).

In order to facilitate allowance, applicants have amended Claims 18 and 20 to specify that the NO or NO modulating compound is complexed to the macromer composition. Support for this amendment is found throughout the specification, for example, on page 13, lines 30-32. Rejected Claims 21-24 are dependent on Claim 20 and incorporate all of the limitations thereof.

Applicants respectfully submit that *Roth et al.* and *Trescony et al.*, alone or in combination, fail to teach an NO or NO modulating compound complexed to a macromer composition as claimed in the amended claims and, therefore, fail to render applicants' method obvious. Particularly, *Roth et al.* and *Trescony et al.* fail to teach, suggest, or provide motivation to use polymeric materials to which NO molecules or NO modulating molecules are complexed. Unlike the claimed method, the biologically active molecules of *Roth et al.* and *Trescony et al.* are entrapped or embedded in the pores of the material.

In view of the foregoing, applicants respectfully assert that the amendment overcomes the rejection of Claims 18 and 20-24 under U.S.C. §103(a). Applicants respectfully assert that *Roth et al.* and *Trescony et al.*, alone or in combination, fail to teach all the elements of amended Claims 18 and 20-24. The cited references fail to teach, suggest, or provide motivation to use the applicants' macromer composition as claimed, and therefore fail to render the applicants' invention obvious.

Applicants respectfully request entry of the amendment to Claims 18 and 20 and withdrawal of the rejection under U.S.C. §103(a).

CONCLUSION

The foregoing is submitted as a full and complete response to the Final Office Action mailed March 24, 2004. Applicants assert that the claims are now in condition for allowance and respectfully request that the application be passed to issuance. If the Examiner believes that any informalities remain in the case, which may be corrected by Examiner's amendment, or that there are any other issues which can be resolved by a telephone interview, a telephone call to the undersigned agent at (404) 815-6102 or to Jamie L. Greene at (404) 745-2473 is respectfully solicited.

The Commissioner is hereby authorized to charge any deficiencies which may be required or credit any overpayment to Deposit Account Number 11-0855.

Respectfully submitted,



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